UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF TEXAS
HOUSTON DIVISION

QUALITY DIAGNOSTICS INTERNATIONAL, LLC,	§	
	§	
Plaintiff,	§	
VS.	§	CIVIL ACTION NO. 4:23-CV-3886
	§	
AZURE BIOTECH, INC., *et al.*,	§	
	§	
Defendants.	§	

MEMORANDUM OPINION AND ORDER

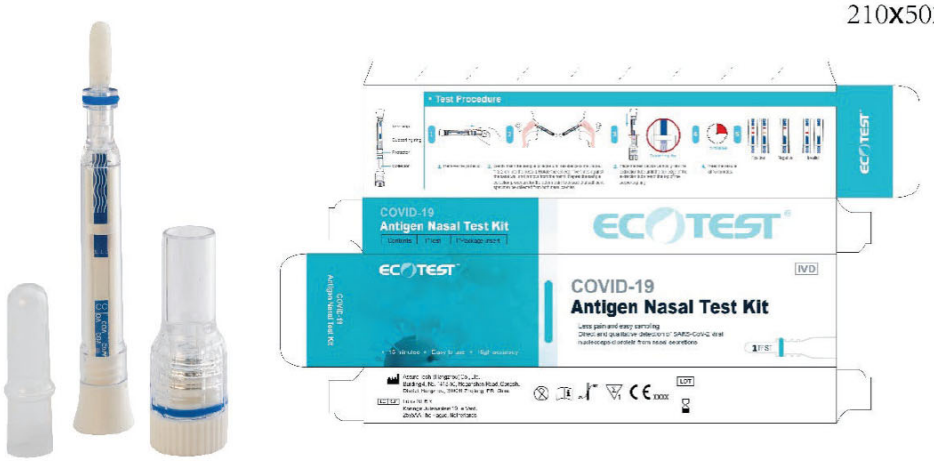
Pending before the Court is a motion for a preliminary injunction filed by the plaintiff, Quality Diagnostics International, LLC ("QDI"). The Court held an evidentiary hearing on the motion on October 30, 2023 and has reviewed the parties' written submissions and the other filings in the case. QDI's motion (Dkt. 1-1) is **DENIED**.

I. BACKGROUND

This case involves a dispute over the distribution rights to COVID-19 testing kits. QDI and Defendant Assure Tech (Hangzhou) Co., Ltd. ("Assure Tech") executed an agreement whereby, according to QDI's complaint, QDI would be "the exclusive distributor . . . in the United States" of this COVID-19 testing kit ("the Ecotest"), which is manufactured by Assure Tech:

Nasal test：Ecotest COVID-19 Antigen Nasal Test Kit

210X50X25mm



Dkt. 1 at pp. 2, 5, 34.

QDI filed an application for emergency use authorization with the United States Food and Drug Administration ("FDA") regarding the Ecotest, but the FDA "deprioritized" the application two and a half months after QDI filed it, meaning that QDI failed to obtain (and still lacks) the requisite regulatory approval to distribute the Ecotest. (Dkt. 1 at p. 4; Dkt. 26 at pp. 39–40). After the FDA's decision, QDI briefed Assure Tech regarding the FDA's proffered reasons for the deprioritization and laid out a strategy to assuage the FDA's concerns. (Dkt. 1 at p. 4; Dkt. 26 at pp. 43–44).

While QDI was trying to get the Ecotest approved for distribution, Assure Tech entered into an agreement with Defendant Azure Biotech, Inc. ("Azure") whereby Azure would distribute this COVID-19 testing kit ("the FaStep"), which is also manufactured by Assure Tech:

Dkt. 1 at pp. 5, 60.

Azure filed an application for emergency use authorization with the FDA regarding the FaStep, and the FDA granted the application. (Dkt. 1 at p. 5). According to QDI, Azure has been awarded a $61.2 million contract to provide the FaStep to the United States government, and Walgreens is now selling the FaStep. (Dkt. 1 at p. 5).

QDI contends that the Ecotest and the FaStep are "virtually identical" and that "Assure Tech utilized QDI's confidential information" to both "gain approval of the FaStep without encountering the problems experienced by QDI" and "evade its obligations to QDI" under the Ecotest distribution agreement. (Dkt. 1 at p. 5; Dkt. 1-1 at p. 3). QDI has sued Assure Tech for breach of contract; has sued Azure for tortious interference with existing and prospective contractual relations; and has sued both Assure

Tech and Azure for violations of the Defend Trade Secrets Act ("DTSA") and the Texas Uniform Trade Secrets Act. (Dkt. 1 at pp. 5–14).

With its complaint, QDI included a motion for a preliminary injunction "enjoining Assure Tech and Azure from distributing the FaStep in the United States." (Dkt. 1-1 at p. 10). The Court held an evidentiary hearing on QDI's request for a preliminary injunction. (Dkt. 20; Dkt. 26).

II. THE LEGAL STANDARD

The purpose of a preliminary injunction is to preserve the status quo and prevent irreparable harm until the respective rights of the parties can be ascertained during a trial on the merits. *City of Dallas v. Delta Air Lines, Inc.*, 847 F.3d 279, 285 (5th Cir. 2017). In the Fifth Circuit, the following well-established framework generally governs the determination of whether to grant a preliminary injunction:

> To be entitled to a preliminary injunction, the movant must satisfy each of the following equitable factors: (1) a substantial likelihood of success on the merits; (2) a substantial threat of irreparable injury; (3) the threatened injury to the movant outweighs the threatened harm to the party sought to be enjoined; and (4) granting the injunctive relief will not disserve the public interest. Because a preliminary injunction is an extraordinary remedy, it should not be granted unless the movant has clearly carried the burden of persuasion on all four requirements. Failure to sufficiently establish any one of the four factors requires this Court to deny the movant's request for a preliminary injunction.
> *Id*.

The requirements for obtaining a preliminary injunction are stringent in all cases, but "[m]andatory preliminary relief, which goes well beyond simply maintaining the status quo pendente lite, is particularly disfavored, and should not be issued unless the facts and law clearly favor the moving party." *Martinez v. Mathews*, 544 F.2d 1233, 1243

(5th Cir. 1976); *see also Justin Industries, Inc. v. Choctaw Securities, L.P.*, 920 F.2d 262, 268 n. 7 (5th Cir. 1990) ("And because Sutherland is seeking a mandatory injunction, it bears the burden of showing a clear entitlement to the relief under the facts and the law."); *Exhibitors Poster Exchange, Inc. v. National Screen Service Corp.*, 441 F2d 560, 561 (5th Cir. 1971) ("[W]hen a plaintiff applies for a mandatory preliminary injunction, such relief should not be granted except in rare instances in which the facts and law are clearly in favor of the moving party.") (quotation marks omitted); *Roark v. Individuals of Federal Bureau of Prisons, Former and Current*, 558 Fed. App'x 471, 472 (5th Cir. 2014).

III. ANALYSIS

The injunction sought by QDI does not maintain the status quo and is instead mandatory in nature, as it would require Assure Tech and Azure to stop distributing the FaStep test in the United States.[1] (Dkt. 1-1 at p. 10). Even if the Court sets aside the first relevant factor and assumes, without deciding, that QDI has shown a substantial likelihood of success on the merits, QDI has fallen short of showing its entitlement to mandatory preliminary relief.

[1] At the evidentiary hearing on its motion, QDI appeared to suggest that it was seeking, in the alternative, an order compelling Assure Tech to designate QDI as a "sub-distributor" for FaStep. (Dkt. 26 at pp. 76–79). However, QDI did not include this request in either its complaint or its motion for a preliminary injunction; QDI's written motion flatly (and only) requests "an order enjoining Assure Tech and Azure from distributing the FaStep in the United States." (Dkt. 1-1 at p. 10). Moreover, QDI did not present sufficient evidence to establish how such a "sub-distributor" designation could be accomplished or, more importantly, whether it could be accomplished without compelling the FDA (which is not a party to this case) to facilitate it. In any event, even QDI's alternative request constitutes a request for a mandatory injunction.

a. Threat of irreparable injury

"The extraordinary equitable remedy of an injunction requires that the [movant] demonstrate that, without injunctive relief, he will suffer an irreparable injury for which damages are an inadequate remedy." *Jones v. American Council on Exercise*, 245 F. Supp. 3d 853, 867 (S.D. Tex. 2017) (quotation marks omitted). "[T]he injury at issue must be actual and imminent, not speculative or remote." *Allied Home Mortgage Corp. v. Donovan*, 830 F. Supp. 2d 223, 227 (S.D. Tex. 2011).

QDI has not satisfied this element. Though QDI correctly notes that "[i]rreparable injury may be shown where a business 'would suffer a substantial loss of business and perhaps even bankruptcy' absent injunctive relief[,]" *id*. at 228 (quoting *Doran v. Salem Inn, Inc.*, 422 U.S. 922, 932 (1975)), the company's only pieces of evidence are its verified complaint and the testimony of its CEO, neither of which provides specific information clearly establishing that damages are an inadequate remedy in this case. For instance, in its motion for a preliminary injunction, QDI contends that "Defendants' intentional tactics to undermine the [Ecotest distribution] Agreement, if allowed to continue, will seriously threaten QDI's ability to continue its operations." (Dkt. 1-1 at p. 8). As evidence, the motion cites paragraph 83 of QDI's verified complaint. (Dkt. 1-1 at p. 8). In its entirety, that paragraph reads:

> 83. As a direct and proximate result of Defendants' misappropriation, QDI has suffered irreparable harm, injuries, and damages in an amount exceeding $75,000, and will continue to suffer irreparable harm, injury, and damages including but not limited to loss of relevant market share, injury to business reputation and goodwill, loss of profits, being forced to cease operations, and attorneys' fees and costs. Defendants have gained an unfair competitive advantage and other unjust enrichment through the misuse of QDI's trade secrets.

Dkt. 1 at p. 12.

These vague, conclusory statements do not clearly demonstrate that, without injunctive relief, QDI will suffer an irreparable injury for which damages are an inadequate remedy. Moreover, QDI cuts against its own argument in its reply brief by requesting, for the first time, a "reasonable royalty" under the DTSA. (Dkt. 22 at p. 5). *See* 18 U.S.C. § 1836(b)(3). In its discussion of the reasonable-royalty remedy, QDI admits that "there is not enough evidence in the record for this Court to determine such a royalty" and that the parties would have to engage in "discovery surrounding communications between Defendants, the history of the FaStep pen test, and sales information" in order "to determine what the [FaStep] test costs, sells for, or what specific information Azure used and the value of that specific information." (Dkt. 22 at p. 6). By admitting not only that a royalty payment is acceptable but that it must conduct somewhat extensive discovery to ascertain the contours of that proposed royalty, QDI considerably undermines its contention that it will not survive unless the Court stops Assure Tech and Azure from distributing the FaStep test during the pendency of this case.

In any event, it is not clear how the specific relief that QDI seeks in its motion—a mandatory injunction barring Assure Tech and Azure from distributing the FaStep test in the United States—would improve QDI's financial position. There is no evidence in the record showing that QDI can sell the Ecotest, the FaStep, or any other COVID test without FDA approval, so, judging by the available record, an injunction barring Assure Tech and Azure from selling the FaStep would simply prevent the sale of both the Ecotest and the FaStep. QDI has not met its burden of persuasion on this factor.

b. Relative weight of threatened harm

QDI has failed to show that the threat of harm faced by QDI if its motion for a preliminary injunction is denied outweighs the threat of harm faced by Assure Tech and Azure if QDI's motion for a preliminary injunction is granted. Again, QDI has presented only vague, conclusory statements to demonstrate that, without injunctive relief, it will suffer an irreparable injury for which damages are an inadequate remedy. On the other hand, Assure Tech and Azure will suffer clear harm: they will not be able to sell the FaStep in the United States, despite having received the necessary regulatory approval. QDI has not met its burden of persuasion on this factor.

c. The public interest

QDI has failed to show that granting its motion for a preliminary injunction will not disserve the public interest. As mentioned above, there is no evidence in the record showing that QDI can sell the Ecotest, the FaStep, or any other COVID test without FDA approval, so, judging by the available record, an injunction barring Assure Tech and Azure from selling the FaStep would simply prevent the sale of both the Ecotest and the

FaStep. Instead of losing one COVID test, the public would lose two. To enter such an injunction would disserve the public interest. QDI has not met its burden of persuasion on this factor.

IV. CONCLUSION

QDI's motion for a preliminary injunction (Dkt. 1-1) is **DENIED**.

SIGNED at Houston, Texas on January 18, 2024.

George C. Hanks Jr.

GEORGE C. HANKS, JR.
UNITED STATES DISTRICT JUDGE